# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

# Note to Reader January 15, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. It is not meant to be a summary of all current information regarding the chemical. Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director

Special Review and Reregistration Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

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**- 8** 1999

<u>MEMORANDUM</u>

OPP PUBLIC DOCKET

SUBJECT:

Methidathion. Reregistration Case No. 0034, Chemical No. 100301. Product

1) clan O Smith

and Residue Chemistry Chapters for the Reregistration Eligibility Decision

Document (RED). CBRS No.16950. DP Barcode D223665.

FROM:

William O Smith, Chemist

Chemistry Pilot Review Team

Chemistry Branch II: Reregistration Support

Health Effects Division (7509C)

THRU:

Edward Zager, Branch Chief

Chemistry Branch II: Reregistration Support

Health Effects Division (7509C)

TO:

Paula Deschamp

Risk Characterization and Analysis Branch

Health Effects Division (7509C)

Attached are the Product and Residue Chemistry Chapters for the Methidathion RED. This information was compiled by Dynamac Corporation under supervision of CBRS, HED. These chapters have undergone secondary review in CBRS and have been revised to reflect Agency policies.

All product chemistry data submitted in support of the reregistration of methidathion have been evaluated and have been found to be satisfactory. CBRS has no objections to the reregistration of methidathion with respect to product chemistry.

All residue chemistry data submissions in support of the reregistration of methidathion have been reviewed. Field residue data must be submitted for cotton gin byproducts and a tolerance must be proposed for this commodity when adequate field residue data have been submitted. Additionally, tolerance revisions have been required. Tolerances for grass, grass hay, alfalfa and alfalfa hay should be revoked as the use on alfalfa/timothy is to be canceled. The tolerances on clover and clover hay should also be revoked as the use on clover grown for seed is a non-food use. Tolerances on potatoes should be revoked because there are no

registered uses on this crop. Contingent upon the above cancellations/revocations, there will be no further need for tolerances on meat, milk, poultry and eggs; these tolerances should also be revoked. The tolerance on citrus fruits (except mandarins) should be increased from 2 ppm to 4 ppm. No Section 409 tolerances are required; however, a Section 701 MRL should be established for residues in citrus oil.

CBRS believes the existing data constitute a substantially complete database sufficient to assess dietary exposure and has no objections to the reregistration of methidathion with respect to residue chemistry.

cc: Reviewer(W. Smith), Reg. Std. File, RF, SF, Circ.

RDI:Pilot Team:6/6/96:RPerfetti:6/10/96

7509C:CBRS:CM#2:Rm805A 305-5353:WSmith:6/5/96

# **METHIDATHION**

# REREGISTRATION ELIGIBILITY DECISION:

## PRODUCT CHEMISTRY CONSIDERATIONS

Shaughnessy No. 100301; Case No. 0034

# DESCRIPTION OF CHEMICAL

Methidathion (*O*,*O*-dimethyl phosphorodithioate, *S*-ester with 4-(mercaptomethyl-2-methoxy-1,3,4-thiadiazolin-5-one) is an insecticide/acaricide registered for control of a broad spectrum of agricultural insect and mite pests on various crops, predominantly alfalfa, citrus, and cotton.

$$S = N S P OCH_3$$

$$H_2CO$$

 $Empirical \ Formula: \qquad \qquad C_6 H_{11} N_2 O_4 PS_3$ 

Molecular Weight: 302.3 CAS Registry No.: 950-37-8 Shaughnessy No.: 100301

# <u>IDENTIFICATION OF ACTIVE INGREDIENT</u>

Methidathion is a colorless to white crystalline solid with an organophosphate odor and a melting point of 39-40 C. Methidathion is slightly soluble in water at 240 ppm (20 C), and is soluble in benzene, acetone, methanol, and xylene at >60 g/100 mL (25 C). Methidathion is only moderately soluble in chloroform and dichloromethane.

## MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 10/18/95 identified two methidathion manufacturing-use products (MPs) registered to Ciba-Geigy Corporation under Shaughnessy No. 100301: the 95% technical (T; EPA Reg. No. 100-530) and the 50% formulation intermediate (FI; EPA Reg. No. 100-567). Only the Ciba-Geigy 95% T and 50% FI are subject to a reregistration eligibility decision.

### REGULATORY BACKGROUND

The Methidathion Guidance Document dated 1/13/83 required additional product chemistry data for the methidathion TGAI and MPs. The Methidathion Final Reregistration Standard and Tolerance Reassessment (FRSTR) dated 6/7/88 evaluated data submitted in response to the Guidance Document, and required that recent product chemistry data be submitted to fulfill remaining requirements. Additional data were required for all 61 and 62 series GLNs, and for some 63 series GLNs. The current status of the product chemistry data requirements for Ciba-Geigy methidathion MPs is presented in the attached data summary tables.

# **CONCLUSIONS**

All pertinent data requirements are satisfied for the Ciba-Geigy methidathion 95% TGAI/T and 50% FI. Provided that the registrant <u>either</u> certifies that the suppliers of beginning materials and the manufacturing processes for the methidathion T and MP have not changed since the last comprehensive product chemistry review <u>or</u> submits complete updated product chemistry data packages, CBRS has no objections to the reregistration of methidathion with respect to product chemistry data requirements.

# AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s).: 8424 DP Barcode(s): D167622

Subject: Methidathion (ID # 100301). Ciba-Geigy Response to the Methidathion

Registration Standard: Product Chemistry.

From: F. Toghrol
To: L. Rossi
Dated: 2/20/92

MRID(s): 41863501 through 41863503

CBRS No(s).: 8425 DP Barcode(s): D167625

Subject: Methidathion. Ciba-Geigy Response to Guidance Document Dated 9/88.

Product Chemistry Data Requirements for 50% FI.

From: L. Cheng
To: L. Rossi
Dated: 5/7/92

MRID(s): 41863504 through 41863506

CBRS No(s).: 12158 DP Barcode(s): D192769

Subject: Response to the Methidathion Reregistration Standard: Product Chemistry

From: R. Perfetti

To: L. Rossi and A. Rathman

Dated: 9/16/93

MRID(s): 42789701 through 42789703

CBRS No(s).: 15702 DP Barcode(s): D218276

Subject: Product Chemistry for Methidathion 50S. Chemical No. 100301. Case No.

0034. Registration No. 100-567. GLN's 61-1, 61-2, 61-3, 62-2, 62-3, 63-7,

63-12, 63-14, 63-16, 63-19, 63-20.

From: W. Smith

To: B. O'Keefe/L. Schnaubelt

Dated: 11/15/95

MRID(s): 43733301 through 43733305

### PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

# References (cited):

00011347 Ciba-Geigy Corporation (1977) Chemical Data Section for Methidathion. (Unpublished study received Jun 28, 1977 under 100-530; CDL:230756-A).

00131026 Ciba-Geigy Corp. (1982) [Chemistry of Technical Methidathion]. (Compilation; unpublished study received Sep 1, 1983 under 100-530; CDL:251155-A).

00142590 Ciba-Geigy Corp. (1983) Ciba-Geigy Technical Methidathion: Methidathion 505: Response to Product Chemistry Comments in EPA Letter of December 1, 1983. Unpublished study. 2 p.

00155944 Ciba-Geigy Corp. (1986?) Technical Methidathion: Density. Unpublished study. 1 p.

40079802 Gale, T. (1986) Methidathion: Analytical Short Report Product Chemistry Data: Study No. ASGSR-86-18. Unpublished compilation prepared by Ciba-Geigy Corp. 15 p.

41863501 Lail, L. (1991) Technical Methidathion: Product Chemistry: Lab Project Number: PC-91-001. Unpublished study prepared by Ciba Geigy Corp. 60 p.

41863502 Lail, L. (1991) Technical Methidathion: Product Chemistry: Lab Project Number: PC-91-001. Unpublished study prepared by Ciba Geigy Corp. 100 p.

41863503 Lail, L. (1991) Technical Methidathion: Product Chemistry: Lab Project Number: PC-91-001. Unpublished study prepared by Ciba Geigy Corp. 66 p.

41863504 Lail, L. (1991) Methidathion 50S: Product Chemistry: Lab Project Number: PC-91-004. Unpublished study prepared by Ciba Geigy Corp. 69 p.

41863505 Lail, L. (1991) Methidathion 50S: Product Chemistry: Lab Project Number: PC-91-004. Unpublished study prepared by Ciba Geigy Corp. 78 p.

41863506 Lail, L. (1991) Methidathion 50S: Product Chemistry: Lab Project Number: PC-91-004. Unpublished study prepared by Ciba Geigy Corp. 9 p.

42789701 Jackson, W. (1993) Technical Methidathion: Supplement to Product Chemistry. Unpublished study prepared by Ciba-Geigy Corp. 17 p.

42789702 Jackson, W. (1993) Supplement to Product Chemistry: Technical Methidathion. Unpublished study prepared by Ciba-Geigy Corp. 9 p.

42789703 Jackson, W. (1993) Supplement to Product Chemistry (Series 63): Technical Methidathion. Unpublished study prepared by Ciba-Geigy Corp. 6 p.

43733301 Lail, L. (1995) Technical Methidathion Product Chemistry: (Product Identity and Composition): Supplement: Lab Project Number: PC-95-027: CC-DOC\PRODCHEM\95027.DOC. Unpublished study prepared by Ciba-Geigy Corp. 15 p.

43733302 Lail, L. (1995) Methidathion 50S Product Chemistry: (Product Identity and Composition): Supplement: Lab Project Number: PC-95-028: Z:\CC-DOC\PRODCHEM\M-50S.DOC. Unpublished study prepared by Ciba-Geigy Corp. 15 p.

43733303 Lail, L. (1995) Technical Methidathion Product Chemistry: (Analysis and Certification of Ingredient Limits): Supplement: Lab Project Number: PC-95-027: Z:\CC-DOC\PRODCHEM\95027-B.DOC. Unpublished study prepared by Ciba-Geigy Corp. 52 p.

43733304 Lail, L. (1995) Methidathion 50S Product Chemistry: (Analysis and Certification of Ingredient Limits): Supplement: Lab Project Number: PC-95-028: Z:\CC-DOC\PRODCHEM\M-50S-62.DOC. Unpublished study prepared by Ciba-Geigy Corp. 55 p.

43733305 Lail, L. (1995) Technical Methidathion & Methidathion 50S Product Chemistry: (Physical and Chemical Characteristics): Supplement: Lab Project Number: PC-95-027: PC-95-028: Z:\CC-DOC\PRODCHEM\95027-C.DOC. Unpublished study prepared by Ciba-Geigy Corp. 5 p.

Case No. 0034

Chemical No. 100301

Case Name: Methidathion

Registrant: Ciba-Geigy Corporation

Product(s): 95% T (EPA Reg. No. 100-530)

# PRODUCT CHEMISTRY DATA SUMMARY

	TRODUCT CHEMISTRI DATA	A DUMINIAN I	
Guideline	Description	Are Data Requirements	MDID Namba h
Number	Requirement	Fulfilled? a	MRID Number b
61-1	Product Identity and Disclosure of Ingredients	Y	41863501, 42789701 °, CSF dated 7/20/95 d
61-2	Starting Materials and Manufacturing Process	Y	<b>00011347</b> , <u>41863501</u> , 42789701 °
61-3	Discussion of Formation of Impurities	Y	<b>00142590</b> , <b>40079802</b> , 41863501, 42789701 °
62-1	Preliminary Analysis	Y	<b>00131026</b> , <b>40079802</b> , 41863502
62-2	Certification of Ingredient Limits	Y	<b>00131026</b> , <b>00142590</b> , <b>40079802</b> , <u>41863502</u> , 42789702 °, CSF dated 7/20/95 <sup>d</sup>
62-3	Analytical Methods to Verify the Certified Limits	Y	<b>00131026</b> , <b>40079802</b> , 41863502, 42789702 °
63-2	Color	Y	<b>00011347</b> , <b>40079802</b> , 41863503, 42789703 °
63-3	Physical State	Y	<b>40079802</b> , <u>41863503</u> , 42789703 °
63-4	Odor	Y	<b>00011347</b> , <u>41863503</u> , 42789703 °
63-5	Melting Point	Y	<b>00011347</b> , <u>41863503</u> , 42789703 °
63-6	Boiling Point	N/A e	
63-7	Density, Bulk Density or Specific Gravity	Y	<b>00155944</b> , <u>41863503</u> , 42789703 °
63-8	Solubility	Y	<b>00011347</b> , <b>00131026</b> , 41863503, 42789703 °
63-9	Vapor Pressure	Y	<b>00011347</b> , <u>41863503</u> , 42789703 °
63-10	Dissociation Constant	Y	41863503, 42789703 °
63-11	Octanol/Water Partition Coefficient	Y	<b>00131026</b> , <u>41863503</u> , 42789703 °
63-12	pH	Y	<b>00131026</b> , <b>00142590</b> , 41863503, 42789703 °
63-13	Stability	Y	<b>00011347</b> , <b>40079802</b> , 41863503, 42789703 °

		Are Data	
Guideline		Requirements	
Number	Requirement	Fulfilled? <sup>a</sup>	MRID Number b
63-14	Oxidizing or Reducing Action	Y	42789703 °

Guideline Number	Requirement	Are Data Requirements Fulfilled? <sup>a</sup>	MRID Number b
63-15	Flammability	Y	42789703 °
63-16	Explodability	Y	42789703 °
63-17	Storage Stability	Y	42789703 °
63-18	Viscosity	N/A e	
63-19	Miscibility	N/A e	
63-20	Corrosion Characteristics	Y	42789703 °

<sup>&</sup>lt;sup>a</sup> Y = Yes; N = No; N/A = Not Applicable.

<sup>&</sup>lt;sup>b</sup> **Bolded** citations were reviewed in the Methidathion FRSTR dated 6/7/88; <u>underlined</u> citations were reviewed under CBRS No. 8424, D167622, 2/20/92, F. Toghrol; and all remaining citations were reviewed as noted.

<sup>&</sup>lt;sup>c</sup> CBRS No. 12158, D192769, 9/16/93, R. Perfetti.

<sup>&</sup>lt;sup>d</sup> CBRS No. 15702, D218276, 11/15/95, W. Smith.

<sup>&</sup>lt;sup>e</sup> Data are not required because the TGAI/MP is a solid at room temperature.

Case No. 0034

Chemical No. 100301

Case Name: Methidathion

Registrant: Ciba-Geigy Corporation

Product(s): 50% FI (EPA Reg. No. 100-567)

# PRODUCT CHEMISTRY DATA SUMMARY

	TRODUCT CHEWISTRY DATA	Are Data	
Guideline		Requirements	
Number	Requirement	Fulfilled? a	MRID Number b
61-1	Product Identity and Disclosure of Ingredients	Y	<u>41863504</u> ,
			CSF dated 7/20/95
61-2	Starting Materials and Manufacturing Process	Y	<b>00131026</b> , <u>41863504</u> ,
			43733301, 43733302
61-3	Discussion of Formation of Impurities	Y	<u>41863504</u> , 43733301,
		37/4 0	43733302
62-1	Preliminary Analysis	N/A °	41863505
62-2	Certification of Ingredient Limits	Y	41863505,
62.2	Analysis I Made Jan Walfords Coulffeld Coulffeld	Y	CSF dated 7/20/95
62-3 63-2	Analytical Methods to Verify the Certified Limits Color	Y	<u>41863505</u> , 43733304
		Y	<b>00131026</b> , <u>41863506</u>
63-3	Physical State	Y	<b>00131026</b> , <u>41863506</u>
63-4	Odor		<b>00131026</b> , <u>41863506</u>
63-5	Melting Point	N/A °	
63-6	Boiling Point	N/A °	00101006 11060506
63-7	Density, Bulk Density or Specific Gravity	Y	<b>00131026</b> , <u>41863506</u> , 43733305
63-8	Solubility	N/A c	
63-9	Vapor Pressure	N/A c	
63-10	Dissociation Constant	N/A c	
63-11	Octanol/Water Partition Coefficient	N/A c	
63-12	pH	Y	00131026, 00142590,
			<u>41863506</u> , 43733305
63-13	Stability	N/A c	
63-14	Oxidizing or Reducing Action	Y	<b>00131026</b> , <u>41863506</u> ,
			43733305
63-15	Flammability	Y	<b>00131026</b> , <u>41863506</u>
63-16	Explodability	Y	<b>00131026</b> , <u>41863506</u> , 43733305
63-17	Storage Stability	Y	<b>00131026</b> , <u>41863506</u>
63-18	Viscosity	Y	<b>00131026</b> , <u>41863506</u>
63-19	Miscibility	Y	<b>00131026</b> , <u>41863506</u> ,
			43733305
63-20	Corrosion Characteristics	Y	<b>00131026</b> , <u>41863506</u> ,
			43733305

<sup>a</sup> Y = Yes; N = No; N/A = Not Applicable.

<sup>&</sup>lt;sup>b</sup> **Bolded** citations were reviewed in the Methidathion FRSTR dated 6/7/88; <u>underlined</u> citations were reviewed under CBRS No. 8425, D167625, 5/7/92, L. Cheng; and all other citations were reviewed under CBRS No. 15702, D218276, 11/15/95, W. Smith.

<sup>&</sup>lt;sup>c</sup> This data requirement will be satisfied by data for the technical source product (TGAI).

# Methidathion Shaughnessy No. 100301; Case 0034 **Reregistration Eligibility Decision January 19, 1996 Contract No. 68-D4-0010 Submitted to: U.S. Environmental Protection Agency** Arlington, VA **Submitted by: Dynamac Corporation** 1910 Sedwick Road **Building 100, Suite B Durham, NC 27713**

# Methidathion

# REREGISTRATION ELIGIBILITY DECISION

# RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 100301; Case No. 0034

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# Methidathion

# REREGISTRATION ELIGIBILITY DECISION

# RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 100301; Case No. 0034

# INTRODUCTION

Methidathion (S-[(5-methoxy-2-oxo-1,3,4-thiadiazole-3-(2H)-yl) methyl] O,O-dimethyl-phosphorodithioate) is an insecticide registered for foliar application to alfalfa, almonds, artichokes, carambola, citrus fruits, clover, cotton, kiwifruit, longans, mangos, olives, pecans, pome fruits, safflower, sorghum (grain), stone fruits, sugar apples, sunflower, timothy, tobacco, and walnuts, using ground or aerial equipment. Three end-use products, including a wettable powder (WP) and two emulsifiable concentrate (EC) formulations are registered for use on food and feed crops.

## REGULATORY BACKGROUND

The Methidathion Guidance Document was issued 1/83. Methidathion was the subject of a Final Reregistration Standard and Tolerance Reassessment (FRSTR) issued in 1988. These documents summarized regulatory conclusions regarding the available residue chemistry data. The FRSTR specified that additional data were required for reregistration purposes. Several submissions of data have been received since the FRSTR. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration eligibility of methidathion.

Tolerances ranging from 0.05-12 ppm have been established for residues of methidathion in/on plant commodities [40 CFR §180.298(a)]. Tolerances of 0.03-0.05 ppm have been established for the combined residues of methidathion, its oxygen analog (S-[(5-methoxy-2-oxo-1,3,4-thiadiazole-3-(2H)-yl)methyl] O,O-dimethyl-phosphorothioate), its sulfoxide metabolite (2-methoxy-4-(methylsulfinylmethyl)-1,3,4-thiadiazole-5-one), and its sulfone metabolite (2-methoxy-4-(methylsulfonylmethyl)-1,3,4-thiadiazole-5-one) in animal commodities [40 CFR §180.298(b)]. Tolerances with regional registration of 0.1-0.2 ppm have been established for residues of methidathion in carambola, kiwifruit, longan, and sugar apple [40 CFR §180.298(c)]. The molecular structures of methidathion and its currently regulated metabolites are depicted in Figure 1. The HED metabolism committee has determined that the residue of concern is methidathion *per se* (R. Perfetti, CBRS memorandum of 4/6/95).

The Agency has recently updated the Livestock Feeds Table [Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, Table II (September, 1995)]. Additional residue data are now required for some commodities as a result of changes in Table II; these data requirements have

been incorporated into this document. These new data requirements will be imposed at the issuance of the Methidathion RED but should not impinge on the reregistration eligibility decision for methidathion. The need for additional tolerances and for revisions to exposure/risk assessments will be determined upon receipt of the required residue chemistry data.

Figure 1. Chemical names and structures of methidathion and its regulated metabolites.

Figure 1. Chemical names and structures of methidati	mon and its regulated metabolites.
Common Name/ Chemical Name and Code	Structure
Methidathion  S-[(5-methoxy-2-oxo-1,3,4-thiadiazole-3-(2H)-yl)methyl] O,O-dimethyl-phosphorodithioate  GS-13005	$\begin{array}{c c} O & S \\ \parallel & \parallel \\ N & S & OCH_3 \end{array}$ $H_3CO$
Methidathion oxygen analog  S-[(5-methoxy-2-oxo-1,3,4-thiadiazole-3-(2H)- yl)methyl] O,O-dimethyl-phosphorothioate  GS-13007	O O    S    P OCH <sub>3</sub> N OCH <sub>3</sub>
Methidathion sulfoxide  5-methoxy-3-methylsulfinylmethyl-1,3,4-thiadiazole- 2-one  GS-28370	$\begin{array}{c} O \\ S \\ N \\ S \\ N \\ O \\ \end{array}$ $H_3CO$ $CH_3$ $0$
Methidathion sulfone  5-methoxy-3-methylsulfonylmethyl-1,3,4-thiadiazole- 2-one  GS-28369	S O O CH <sub>3</sub> N O CH <sub>3</sub> O O CH <sub>3</sub>

# **SUMMARY OF SCIENCE FINDINGS**

# GLN 171-3: Directions for Use

A REFs search conducted 10/18/95 indicated that there are three methidathion end-use products (EPs) with food/feed uses registered to Ciba Geigy Corp. These EPs are presented below.

EPA Reg. No.	Acceptance Date	Formulation Class	Product Name
100-501 <sup>a</sup>	3/95	2 lb/gal EC	Supracide® 2E Insecticide-Miticide
100-719	5/94	2 lb/gal EC	Supracide® Insecticide-Miticide
100-754 <sup>b</sup>	5/95	25% WP	Supracide® 25 WP Insecticide-Miticide

<sup>&</sup>lt;sup>a</sup> Includes CA770039, CA900002, FL920005, ID930003, OR930007, and WA940019.

The restricted entry interval is 48 hours for applications of  $\le 2$  lb ai/A or 14 days for applications at > 2 lb ai/A.

A comprehensive summary of the registered food/feed use patterns of methidathion, based on the product labels registered to Ciba Geigy Corp., is presented in Table A. A tabular summary of the residue chemistry science assessments for reregistration of methidathion is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of methidathion food/feed uses are based on the use patterns registered by the basic producer, Ciba Geigy Corp. When enduse product DCIs are developed (e.g., at issuance of the RED), RD should require that all enduse product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

These labels must be revised to delete the restriction on feeding cotton gin trash to livestock. The feed uses on alfalfa and timothy need to be canceled, as the basic producer is not supporting these uses. The SLN label for use on clover grown for seed must be amended to include restrictions to prevent food or feed use of treated plant parts.

<u>GLN 171-4 (a)</u>: <u>Plant Metabolism</u>: The qualitative nature of the residue in plants is adequately understood based on studies with [<sup>14</sup>C]methidathion on cotton, tomato, artichokes, and citrus. Methidathion *per se* is the residue of concern.

<u>GLN 171-4 (b)</u>: <u>Animal Metabolism</u>: Adequate goat and poultry metabolism studies are available. Methidathion *per se* is the residue of concern. The Agency has determined that methidathion represents a 40 CFR §180.6(a)(3) situation in that there is no reasonable expectation of finite residues in animal commodities. Therefore, residues in livestock commodities are not to

b Includes WA940020.

be regulated. This conclusion assumes cancellation of the feed uses on alfalfa, clover, and timothy and revocation of tolerances on these commodities.

GLN 171-4 (c/d): Residue Analytical Methods: Adequate methods are available for data collection and tolerance enforcement pertaining to methidathion *per se* in/on plant commodities. Method I in Pesticide Analytical Manual (PAM), Vol. II is a GLC/flame photometric detection (FPD) method. Methods used for data collection include methods based on the PAM, Vol. II method and other GC methods. There are no requirements for enforcement methodology for animal commodities as the tolerances for animal commodities are to be revoked.

The FDA PESTDATA database dated 1/94 (PAM, Volume I, Appendix I) indicates that methidathion is completely recovered (>80%) by Multiresidue Methods Section 302 (Luke method; Protocol D), exhibited small (<50%) recovery using Methods Section 303 (Mills, Onley, Gaither method; Protocol E, non-fatty), and is completely or partially (50-80%) recovered, depending on the Florisil elution system used, by Multiresidue Method Section 304 (Mills fatty food method; Protocol E, fatty).

GLN 171-4 (e): Storage Stability Data: Storage stability data are available on alfalfa forage and hay, clover forage, corn forage, corn fodder, corn grain, cottonseed, cottonseed refined oil, kiwifruit, and oranges. However, data are required pertaining to the storage intervals and conditions of crop samples from several studies. The studies lacking storage information are listed in Table 14 of CBRS Nos. 10870 and 11158 (DP Barcodes D184576 and 186643; 3/2/93; R. Perfetti).

<u>GLN 171-4 (k)</u>: <u>Magnitude of the Residue in Plants:</u> The reregistration requirements are satisfied for magnitude of the residue in/on, almond hulls, artichokes, carambola, citrus fruits, cottonseed, pome fruits, stone fruits, kiwifruit, longan, mandarins, mangos, nuts, olives, peaches, pecans, safflower seeds, sorghum (fodder, forage, and grain), sugar apple, sunflower seeds, tobacco, and walnuts.

Methidathion residue data requirements for cotton gin byproducts which result from changes in the Livestock Feeds Table (TABLE II, September, 1995) should be imposed at this time. However, this requirement should not impinge on the reregistration eligibility decision for methidathion. Data are required on methidathion in the plant byproducts from ginning cotton, consisting of burrs, leaves, stems, lint, and immature seeds. Cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue for the ginning process. At least three field trials for each type of harvesting (stripper and picker) are needed, for a total of six field trials. The need for additional tolerances and revisions to the exposure/risk assessments will be made upon receipt and evaluation of required data.

<u>GLN 171-4 (l)</u>: <u>Magnitude of the Residue in Processed Food/Feed</u>: Adequate data are available to demonstrate that residues do not concentrate in commodities derived from sunflower seed and

these data can be translated to safflower seed. Owing to the use patterns for apples, plums, and olives, finite residues are not expected in the RACs and requirements for processing studies have been waived.

Residues concentrate in citrus oil. Based on a highest average field trial (HAFT) residue value of 3.5 ppm for oranges and an average concentration factor of 118x from 10 processing studies, residues of 412 ppm would be expected in citrus oil. As citrus oil is not ready-to-eat (NRTE) and assuming a dilution factor of 238, dietary exposure to methidathion residues from citrus oil would be 1.7 ppm, lower than the re-assessed tolerance level of 4 ppm for citrus fruit. Therefore, no 409 tolerance is required. A Section 701 MRL of 420 ppm is appropriate for citrus oil.

Seven processing studies on cottonseed indicate an average concentration factor of 1.9x in cottonseed hulls. The highest average field trial (HAFT) residue for cottonseed is <0.01; therfore, residues in cottonseed hulls would not be expected to exceed the established tolerance of 0.2 ppm on the RAC. No Section 409 tolerance or Section 701 MRL is required for cottonseed hulls.

The seven cottonseed processing studies indicate a 1.3x average concentration of residues in refined oil; this does not represent an appreciable concentration. Furthermore, the most recent processing study demonstrated that bleaching refined oil decreased the residues to a level below that in seed and subsequent hydrogenation and deodorization reduced refined oil residues to below the limit of quantitation (<0.05 ppm). Neither a Section 409 tolerance nor a Section 701 MRL is required for refined cottonseed oil.

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs: The HED Metabolism Committee has determined that methidathion represents a 40 CFR §180.6(a)(3) situation in that there is no reasonable expectation of finite residues in animal commodities; therefore, livestock feeding studies and tolerances on livestock commodities are not required. This conclusion regarding the need for tolerances on livestock commodities requires that the registrations/tolerances on alfalfa, clover, and grasses be canceled/revoked. Any additional uses resulting in residues of methidathion in/on livestock feed items may engender the need for tolerances in/on meat, milk, poultry and eggs.

<u>GLN 165-1 and 165-2</u>: Rotational Crops: The available confined rotational crop study is adequate. Field rotational crop data and tolerances for rotated crops are not required.

TABLE A. FOOD/FEED USE PATTERNS SUBJECT TO REREGISTRATION FOR METHIDATHION (CASE 0034).

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps.	Use Limitations <sup>a</sup>
Food/feed uses				
Alfalfa and Timothy				
Foliar Ground, aerial	2 lb/gal EC [WA940019] 25% WP [WA940020]	1	NS	Restricted to Kittitas County, WA; other sites are restricted to seed production. 21-day PHI/PGI. <sup>b</sup>
Almonds				
Foliar Dormant/delayed dormant or cover spray Ground, aerial	2 lb/gal EC [100-501] [100-719] 25% WP [100-754]	3	2	80-day PHI. Do not graze treated areas or feed cover crops to livestock. Do not apply more than one dormant/delayed dormant nor more than one cover spray per season.
Apples, pears				
Foliar Dormant, delayed dormant Ground, aerial	2 lb/gal EC [100-501] [100-719] 25% WP [100-754]	3	1	Apply before blossoms open.  Do not graze treated areas or feed cover crops to livestock.
Apricots, cherries, nectarines, peaches, p	olums, prunes			
Foliar Dormant, delayed dormant Ground, aerial	2 lb/gal EC [100-501] [100-719] 25% WP [100-754]	3	1	Apply before blossoms open.  Do not graze treated areas or feed cover crops to livestock.

Table A. (continued)

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps.	Use Limitations <sup>a</sup>		
Artichokes						
Foliar Ground, aerial	2 lb/gal EC [100-501] [100-719] 25% WP [100-754]	1	8	Do not apply after buds begin to form. 14-day re-treatment interval.		
Carambola						
Foliar Ground	2 lb/gal EC [FL920005]	0.375	3	21-day PHI. 30-day re-treatment interval. Do not graze treated areas.		
Citrus fruit						
Foliar Ground	2 lb/gal EC [100-501] [100-719] 25% WP [100-754]	5	2	14-day PHI. 60-day PHI if applied with oil. Do not apply during the bloom period. Lemons: when used with oil, do not exceed 2.5 lb ai/A or apply more than once per season.		
Cotton						
Foliar Ground, aerial	2 lb/gal EC [100-501] [100-719] 25% WP [100-754]	1 (0.5 after bolls open)	4	14-day PHI. 5- to 7-day retreatment intervals. Do not graze treated plants of feed gin trash to livestock.		

Table A. (continued)

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps.	Use Limitations <sup>a</sup>
Kiwifruit				
Foliar Dormant Ground	2 lb/gal EC [CA900002]	2	1	Do not use after bud break.
Longan				
Foliar Ground	2 lb/gal EC [FL920005]	0.25	2	21-day PHI. 45-day re-treatment interval. Do not graze treated areas.
Mangos				
Foliar Dormant to bloom Ground	2 lb/gal EC [100-501] [100-719]	0.25	5	Apply between post-harvest and bloom stage.  Do not graze treated areas or feed cover crops to livestock.
Olives				
Foliar Post-harvest or pre-bloom period Ground	2 lb/gal EC [100-501] [100-719] 25% WP [100-754]	3	1	Do not apply after buds break. Do not graze treated areas or feed cover crops to livestock.
Pecans (Southern U.S. only)				
Foliar Ground	2 lb/gal EC [100-501] [100-719] 25% WP [100-754]	4	2	60-day PHI.  Do not graze treated areas or feed cover crops to livestock.
Safflower				

Table A. (continued)

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps.	Use Limitations <sup>a</sup>
Foliar Ground, aerial	2 lb/gal EC [100-501] [100-719] 25% WP [100-754]	0.5	3	28-day PHI. Do not graze treated areas. 7- to 14-day re-treatment intervals.
Sorghum				
Foliar Ground, aerial	2 lb/gal EC [100-501] [100-719]	0.5	3	30-day PHI/PGI. 10- to 14-day re-treatment intervals. Use in CO, KS, OK, TX only.
Sugar apple (including sweetsop, anon, a	temoya, and true cust	ard apple)		
Foliar Ground	2 lb/gal EC [FL920005]	0.5	2	14-day PHI. 14-day re-treatment interval. Do not graze treated areas.
Sunflower				
Foliar Ground, aerial	2 lb/gal EC [100-501] [100-719]	0.5	3	50-day PHI. 7-day re-treatment interval. Do not graze treated areas or feed treated forage to livestock.

Table A. (continued)

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps.	Use Limitations <sup>a</sup>
Walnuts  Foliar Dormant/delayed dormant or cover spray. Ground, aerial	2 lb/gal EC [100-501] [100-719] 25% WP [100-754]	2 (EC) 3 (WP)	3	7-day PHI. Do not graze treated areas or feed cover crops to livestock. Do not apply more than one dormant/delayed dormant nor more than one cover spray per season.
Non-food/feed uses				
Alfalfa grown for seed				
Foliar Ground, aerial	2 lb/gal EC [ID930003] [OR930007]	1	NS	Do not apply through irrigation equipment. Do not feed or graze. Seeds may not be used for sprouts. Not for human or animal consumption.
Clover grown for seed				
Foliar Ground, aerial	2 lb/gal EC [CA770039]	1	NS	None
Tobacco				
Foliar Ground	2 lb/gal EC [100-501] [100-719]	1	3	3-day PHI

a The restricted entry interval is 48 hours for applications ≤2 lb ai/A or 14 days for applications >2 lb ai/A.
 b PHI/PGI = preharvest interval or pre-grazing interval.

Table B. Residue Chemistry Science Assessments for Reregistration of Methidathion.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
171-3: Directions for Use	N/A	Yes <sup>2</sup>	See Table A.
171-4 (a): Plant Metabolism	N/A	No	00011317 00022903 00022905 00022907 00022910 00022911 00060895 <b>00154460</b> <b>00154462</b> 05011885 05012174 05013162 40121401 <sup>3</sup> <b>40127811</b> <b>40127812</b> 41902201 <sup>4</sup> 42537101 <sup>5</sup> 42708901 <sup>6</sup> 42708902 <sup>6</sup>
171-4 (b): Animal Metabolism	N/A	No	00011283 00011317 00011335 00011336 00011848 00011936 00022908 00022909 00026090 <b>40127821</b> 42537102 <sup>5</sup> 42537103 <sup>5</sup> 43170001 <sup>7</sup> 43170005 <sup>7</sup> 43399702 <sup>8</sup>
171-4 (c/d): Residue Analytical Methods	N/A	No	00011320 00011324 00011326 00011334 00011337 00011373 00011722 00011843 00011844 00011846 00011852 00020944 00020945 00020979 00029229 00060902 <b>00128127 00154474</b> 05011904 <b>40127804</b> <b>40127805 40127806</b> <b>40341001</b> 42537104 <sup>5</sup> 42537106 <sup>9</sup> 42537107 <sup>5</sup> 42537108 <sup>5</sup> 42708903 <sup>6</sup> 43296401 <sup>10</sup> 43296402 <sup>10</sup>
171-4 (e): Storage Stability	N/A	Yes <sup>11</sup>	00011843 00060902 00154474 <b>40127802</b> <b>40341001</b> 42537109 <sup>5</sup> 42537110 <sup>5</sup> 42537111 <sup>5</sup>

Table B. (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
171-4 (k): Magnitude of the Residue in Plants			
Root and Tuber Vegetables Group			
- Potatoes	0.2 [§180.298(a)]	$No^{12}$	00014404
Citrus Fruits Group			
- Citrus Fruits (except Mandarins)	2.0 [§180.298(a)]	No <sup>13</sup>	00011323 00011425 00011426 00027999 00029221 00029227 00029228 43308802 <sup>14</sup>
- Mandarins	6.0 [§180.298(a)]	No	00011323
Pome Fruits Group	0.05 [§180.298(a)]	No	00012593 00020946
Stone Fruits Group	0.05 [§180.298(a)]	No	00011641 00011642 00011921 00012593 00012594 00012595 00012596 00012597 00012598 00012599 00012600 00012601 00012603 00012604 00020946 00020947 00020948 00020949 00020950 00020951 00020952 00020953 00020954 00020955 00020956 00020957 00020958 00020959 00020967 00020970 00020971
Tree Nuts Group			
- Almond hulls	6.0 [§180.298(a)]	No	00020946 00036942 43308803 <sup>14</sup>
- Nuts	0.05 [§180.298(a)]	No	00011640 00011769 00020946 00036942 43308803 <sup>14</sup>
- Pecans	0.05 [§180.298(a)]	No	00011640
- Walnuts	0.05 [§180.298(a)]	No	00011640 00011769 00020946

Table B. (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
Cereal Grains Group			
- Sorghum, grain	0.2 [§180.298(a)]	No	00011303 00011304 00011305 00014382 00014383 00014384
Forage, Fodder, and Straw of Cereal Grains Group			
- Sorghum, fodder	2.0 [§180.298(a)]	No	00011303 00011304 00011305 00014382 00014383 00014384
- Sorghum, forage	2.0 [§180.298(a)]	No	00011303 00011304 00011305 00014382 00014383 00014384
Grass Forage and Hay Group			
- Grass forage	12 [§180.298(a)]	$No^{15}$	$00011321\ 43308804^{14}$
- Grass hay	12 [§180.298(a)]	$No^{15}$	$00011321\ 43308804^{14}$
Non-grass Animal Feeds Group			
- Alfalfa forage	12 [§180.298(a)]	No <sup>15</sup>	00011318 00011319 00011321 00011340 00012575
- Alfalfa hay	12 [§180.298(a)]	No <sup>15</sup>	00011318 00011319 00011321 00011340 00012575
- Clover forage	12 [§180.298(a)]	$No^{16}$	00011318 0001134
- Clover hay	12 [§180.298(a)]	$No^{16}$	00011318 00011340
Miscellaneous Commodities			
- Artichokes	0.05 [§180.298(a)]	No	00011764
- Carambola	0.1 [§180.298(c)]	No	4115180217
- Cottonseed	0.2 [§180.298(a)]	No	00011325 00115199 00011786 <b>40127804</b>
- Cotton gin byproducts	None	Yes <sup>18</sup>	
- Kiwifruit	0.1 [§180.298(c)]	No	4093130119
- Longan	0.1 [§180.298(c)]	No	4115180217
- Mangos	0.05 [§180.298(a)]	No	00011473 00011474

Table B. (continued).

	Current Must Tolerances, Additional Data		
GLN: Data Requirements	ppm [40 CFR]	Be Submitted?	References <sup>1</sup>
- Olives	0.05 [§180.298(a)]	No	00011456
- Safflower, seed	0.5 [§180.298(a)]	No	00038279 00038280
- Sugar apple	0.2 [§180.298(c)]	No	$41686301^{20}41686302^{20}$
- Sunflower, seeds	0.5 [§180.298(a)]	No	PP#4F1513
- Tobacco	None	No	00011856
171-4(1): Magnitude of the Residues in Processed	l Food/Feed		
- Apples	None	$No^{21}$	
- Citrus	None	$No^{22}$	$00011323\ 43308802^{14}$
- Cottonseed	None	$No^{23}$	00011325 <b>40127804</b>
- Olives	None	$No^{21}$	
- Plums/prunes	None	$No^{21}$	
- Potatoes	None	No	
- Safflower, seed	None	$No^{24}$	
- Sunflower seed	None	$No^{25}$	PP#4F1513
171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs			
- Meat, mbyp, and fat of cattle, goats, hogs, horses, and sheep	0.05 [§180.298(b)]	$No^{26}$	00022574 00078342 00128127
- Milk	0.03 [§180.298(b)]	$No^{26}$	00022574 00078342 00128127
- Meat, mbyp, and fat of poultry	0.05 [§180.298(b)]	$No^{26}$	00011314
- Eggs	0.05 [§180.298(b)]	$No^{26}$	00011314
165-1: Rotational Crops (Confined)	N/A	No	$40094101^{27}41902201^{27}$
165-2: Rotational Crops (Field)	N/A	No	40094102 <sup>27</sup>

References were reviewed in the Methidathion Registration Standard (Guidance Document dated 1/83).
 References in **bold** were reviewed in the 1988 FRSTR. Otherwise, submissions were reviewed as noted.

<sup>2.</sup> The end-use product labels must be revised to delete the restriction on feeding cotton gin trash to livestock. The feed uses on alfalfa and timothy (EPA SLN Nos. WA940019 and WA940020) need to be canceled, as Ciba Geigy is not supporting these uses. The SLN label for use on clover grown for seed (EPA SLN No. CA770039) must be amended to include restrictions to prevent food or feed use of treated plant parts.

- 3. CBRS No. 5140; DP Barcode (none); 6/14/89; R. Schmitt.
- 4. CBRS No. 8422; DP Barcode D167356; 4/1/92; R. Perfetti.
- 5. CBRS Nos. 10870 and 11158; DP Barcodes D184576 and 186643; 3/2/93; R. Perfetti.
- 6. CBRS No. 11683; DP Barcode D189970; 7/28/93; R. Perfetti.
- 7. CBRS No. 13714; DP Barcode D203435; 7/6/95; R. Perfetti.
- 8. CBRS No. (none); DP Barcode D210041; 4/6/95; R. Perfetti.
- 9. CBRS No. (none); DP Barcode (none); 9/17/93; L. Edwards.
- 10. CBTS Nos. 13529/13530; DP Barcodes D216609/216616; 5/9/94; J. Garbus. CBTS Nos. 13982/13983; DP Barcode D204948/204952; 7/28/94; J. Herndon. CBRS No. 14000; DP Barcode D205407; 1/6/95; G. Kramer.
- 11. Information is required pertaining to storage intervals and conditions of crop samples used for residue data to support tolerances. The MRID numbers for studies requiring additional sample storage information are listed in Table 14 of CBRS Nos. 10870 and 11158 (DP Barcodes D184576 and 186643; 3/2/93; R. Perfetti).
- 12. Because there is no registered use, the tolerance for potatoes is to be revoked.
- 13. The available data indicate that residues may exceed the established 2 ppm tolerance in/on citrus fruit (except mandarins) following registered use; residues of 3.4 and 3.6 ppm were observed in oranges harvested 14 and 60 days following two applications of the 2 lb/gal EC formulation at 5 lb ai/A with (60 day PHI) and without oil (14 day PHI). A tolerance increase to 4 ppm would be appropriate.
- 14. CBTS No. 14096; DP Barcode D205743; 4/27/95; G. Kramer.
- 15. This use is to be canceled and the tolerance should be revoked. Alternatively, livestock feeding studies are required to determine tolerance levels on animal commodities.
- 16. The use on clover grown for seed is a non-food use. The label (CA770039) should be amended to bear the appropriate restrictions or the use must be canceled. The tolerance should be revoked.
- 17. DEB No. 5538; DP Barcode (none); 10/24/89; F. Toghrol.
- 18. Methidathion residue data requirements for cotton gin byproducts which result from changes in the Livestock Feeds Table (TABLE II, September, 1995) should be imposed at this time. However, this requirement should not impinge on the reregistration eligibility decision for methidathion. Data are required on methidathion in the plant byproducts from ginning cotton, consisting of burrs, leaves, stems, lint, and immature seeds. Cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue for the ginning process. At least three field trials for each type of harvesting (stripper and picker) are needed, for a total of six field trials. The need for additional tolerances and revisions to the exposure/risk assessments will be made upon receipt and evaluation of required data.
- 19. CBTS No. 4769; DP Barcode (none); 3/16/89; M. Nelson.
- 20. CBTS No. 7298; DP Barcode D158422; 4/22/91; W. Wassell.

- 21. Owing to the use pattern, finite residues are not expected in the RAC. No processing study is required.
- 22. A section 701 MRL of 420 ppm is required for citrus oil.
- 23. No concentration occurs in cottonseed refined oil. Residues in cottonseed hulls are not expected to concentrate enough (1.9x concentration/HAFT <0.1 ppm) to exceed the established tolerance of 0.2 ppm on cottonseed; no Section 409 tolerance or Section 701 MRL is needed for either of these processed commodities.
- 24. Data from sunflower seed can be translated to safflower seed.
- 25. Adequate data are available to indicate that residues do not concentrate in any processed commodity.
- 26. The HED Metabolism Committee has determined that methidathion represents a 40 CFR §180.6(a)(3) situation in that there is no reasonable expectation of finite residues in animal commodities. Therefore, livestock feeding studies and tolerances on livestock commodities are not required. This conclusion regarding the need for tolerances on livestock commodities requires that the registrations/tolerances on alfalfa, clover, and grasses are canceled/revoked. Any additional uses resulting in residues of methidathion in/on livestock feed items may engender the need for tolerances in/on meat, milk, poultry and eggs.
- 27. CBRS No. 12331; DP Barcode D193876; 12/20/93; R. Perfetti.

### TOLERANCE REASSESSMENT SUMMARY

Tolerances for methidathion residues are currently expressed in terms of methidathion *per se* in plant commodities [§180.298(a and c)] and in terms of the combined residues of methidathion, its oxygen analog, and its sulfoxide and sulfone metabolites in animals [40 CFR §180.298(b)]. A summary of the methidathion tolerance reassessment and recommended modifications in commodity definitions are presented in Table C.

Tolerances Listed Under 40 CFR §180.298(a): Adequate data are available to support the established tolerances for methidathion residues in/on almond hulls, pome fruits, artichokes, cottonseed, mandarins, mangos, olives, peaches, pecans, safflower seed, sorghum commodities, stone fruits, sunflower seed, and walnuts. The established tolerance for residues in/on citrus fruit should be increased from 2 ppm to 4 ppm, as residues of 3.4 and 3.5 ppm have been observed following registered use. The commodity definition for "Nuts" should be amended to reflect the correct crop group designation "Tree nuts," and the tolerances for pecans and walnuts, which are covered by the tree nuts group, should be deleted. The tolerance for "Peaches" is not necessary as peaches are covered by the tolerance for residues in/on "Fruits, stone;" therefore we recommend deletion of the tolerance for peaches. The group definitions "Fruits, pome" and "Fruits, stone" should be revised to "Pome fruits" and "Stone fruits," respectively.

The tolerances for grass and grass hay and alfalfa and alfalfa hay should be revoked as the use on alfalfa/timothy is to be canceled. The tolerances on clover and clover hay should be revoked as the use on clover grown for seed is a non-food use.

<u>Tolerances Needed Under 40 CFR §180.298(a)</u>: Residue data are required to determine a tolerance level on cotton gin byproducts.

<u>Tolerances Listed Under 40 CFR §180.298(b)</u>: The tolerances for residues in animal commodities should be revoked, as the Agency has determined that methidathion represents a 40 CFR §180.6(a)(3) situation in that there is no reasonable expectation of finite residues in animal commodities. This conclusion regarding the need for tolerances on livestock commodities requires that the registrations/tolerances on alfalfa, clover and grasses are canceled/revoked. Any additional uses resulting in residues of methidathion in/on livestock feed items may engender the need for tolerances in/on meat, milk, poultry and eggs.

<u>Tolerances (with regional registration) Listed Under 40 CFR §180.298(c)</u>: Adequate data are available to support the established tolerances for methidathion residues in/on carambola, kiwifruit, longan, and sugar apple.

Table C. Tolerance Reassessment Summary for Methidathion.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
	TD 1 11 4 1	1 40 CED 8100 200/	
A1C.1C.		der 40 CFR §180.298(a	
Alfalfa Alfalfa, hay	12 12	Revoke	The use on alfalfa/timothy is to be canceled.
Almonds, hulls	6	6	
Artichokes	0.05	0.05	
Citrus fruits (except mandarins)	2.0	4.0	Residues of 3.4 and 3.6 ppm have been observed following registered use.
Clover	12	Revoke	The use on clover grown for seed
Clover, hay	12		is a non-food use.
Cottonseed	0.2	0.2	
Fruits, pome	0.05	0.05	Pome fruits
Fruits, stone	0.05	0.05	Stone fruits
Grass	12	Revoke	The use on alfalfa/timothy stands
Grass, hay	12		is to be canceled.
Mandarins	6.0	6.0	
Mangos	0.05	0.05	
Nuts	0.05	0.05	Tree Nuts
Olives	0.05	0.05	
Peaches	0.05	Revoke	Peaches are covered by the established tolerance for stone fruits.
Pecans	0.05	Revoke	Pecans will be covered by a tolerance for tree nuts.
Potatoes	0.2	Revoke	No registered use.
Safflower seeds	0.5	0.5	
Sorghum, fodder	2	2	
Sorghum, forage	2	2	
Sorghum, grain	0.2	0.2	
Sunflower seeds	0.5	0.5	
Walnuts	0.05	Revoke	Walnuts will be covered by a tolerance for tree nuts.

18 (continued)

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity  Definition
	Tolerances needed u	nder 40 CFR §180.298(a	a):
Cotton gin byproducts	None	To be determined	Residue data are required to determine the appropriate tolerance level.
	Tolerances listed un	der 40 CFR §180.298(b	):
Cattle, fat	0.05		
Cattle, meat	0.05		
Cattle, mbyp	0.05		
Eggs	0.05		
Goats, fat	0.05	Revoke	Methidathion residues in
Goats, meat	0.05	Revoke	livestock are considered to fall
Goats, mbyp	0.05		under 40 CFR §180.6(a) (3), and tolerances are not required. This conclusion regarding the need for tolerances on livestock commodities requires that the registrations/tolerances on alfalfa, clover and grasses are canceled/revoked. Any additional uses resulting in residues of methidathion in/on livestock feed items may engender the need for
Hogs, fat	0.05		
Hogs, meat	0.05		
Hogs, mbyp	0.05	]	
Horses, fat	0.05		
Horses, meat	0.05		
Horses, mbyp	0.05		
Milk	0.03		
Poultry, fat	0.05		tolerances in/on meat, milk,
Poultry, meat	0.05		poultry and eggs.
Poultry, mbyp	0.05		
Sheep, fat	0.05		
Sheep, meat	0.05		
Sheep, mbyp	0.05		

19 (continued)

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity  Definition		
	Tolerances listed under 40 CFR §180,298(c):				
Carambola	0.1	0.1			
Kiwi fruit	0.1	0.1	Kiwifruit		
Longan	0.1	0.1			
Sugar apple	0.2	0.2			
Section 701 MRL needed					
Citrus oil	None	420	The dilution factor for citrus oil is 238; no Section 409 tolerance is required.		

## **CODEX HARMONIZATION**

Codex MRLs (CXL) are defined in terms of methidathion residues (fat-soluble). This definition is compatible with the HED metabolism committee's recommendation that U.S. tolerances be defined in terms of methidathion *per se*. Codex MRLs and corresponding U.S. tolerances are listed in Table D.

Table D. Codex MRLs (CXL) for methidathion and corresponding U.S. tolerances.

Commodity	Codex MRL (ppm)	U.S Tolerance (ppm) <sup>a</sup>	Compatibility/Comments
Apple	0.5	0.05 (pome fruits)	Harmonization would require a 10x increase in the U.S. tolerance. Given the U.S. use pattern, we recommend against upward revision of the U.S. tolerance.
Apricot	0.2	0.05 (stone fruits)	Harmonization would require a 4x increase in the U.S. tolerance. Given the U.S. use pattern, we recommend against upward revision of the U.S. tolerance.
Cabbages (head)	0.2	None	
Cattle fat	0.02	None	The current U.S. tolerance of 0.05 ppm will be revoked.
Cauliflower	0.2	None	
Cherries	0.2	0.05 (stone fruits)	Harmonization would require a 4x increase in the U.S. tolerance. Given the U.S. use pattern, we recommend against upward revision of the U.S. tolerance.
Common bean (pods and/or mature seeds)	0.1	None	
Cotton seed	0.2	0.2	U.S. tolerance is compatible with Codex MRL.
Cotton seed oil, crude	1	None	Cottonseed crude oil is not subject to regulation by U.S. tolerance.
Edible offal of cattle, pigs, and sheep	0.02	None	The current U.S. tolerance of 0.05 ppm will be revoked.
Eggs	0.02	None	The current U.S. tolerance of 0.05 ppm will be revoked.
Grapes	0.2	None	
Hops, dry	3	None	
Leafy vegetables	0.2	None	
Lemons and limes	2	4 (citrus fruit)	The current use pattern for methidathion on citrus does not permit a lowering of the U.S. tolerance for citrus fruit.
Maize	0.1	None	

21 (continued)

Table D. (continued)

Commodity	Codex MRL (ppm)	U.S Tolerance (ppm) <sup>a</sup>	Compatibility/Comments
Mandarins	5	6	The current use pattern for methidathion on citrus does not permit a lowering of the U.S. tolerance for mandarins.
Meat of cattle, pigs, and sheep	0.02	None	The current U.S. tolerance of 0.05 ppm will be revoked.
Milk	0.0008	None	The current U.S. tolerance of 0.03 ppm will be revoked.
Nectarine	0.2	0.05 (stone fruits)	Harmonization would require a 4x increase in the U.S. tolerance. Given the U.S. use pattern, we recommend against upward revision of the U.S. tolerance.
Oranges, sweet, sour	2	4 (citrus fruit)	The current use pattern for methidathion on citrus does not permit a lowering of the U.S. tolerance for citrus fruit.
Peach	0.2	0.05 (stone fruits)	Harmonization would require a 4x increase in the U.S. tolerance. Given the U.S. use pattern, we recommend against upward revision of the U.S. tolerance.
Pear	0.5	0.05 (pome fruits)	Harmonization would require a 10x increase in the U.S. tolerance. Given the U.S. use pattern, we recommend against upward revision of the U.S. tolerance.
Peas	0.1	None	
Pig fat	0.02	None	The current U.S. tolerance of 0.05 ppm will be revoked.
Plums (including prunes)	0.2	0.05 (stone fruits)	Harmonization would require a 4x increase in the U.S. tolerance. Given the U.S. use pattern, we recommend against upward revision of the U.S. tolerance.
Potato	0.02	0.2	The U.S. tolerance will be revoked owing to lack of registered use.
Poultry fat	0.02	None	The current U.S. tolerance of 0.05 ppm will be revoked.
Poultry meat	0.02	None	The current U.S. tolerance of 0.05 ppm will be revoked.
Poultry, edible offal	0.02	None	The current U.S. tolerance of 0.05 ppm will be revoked.
Shaddocks or pomelos	2	4 (citrus fruit)	The current use pattern for methidathion on citrus does not permit a lowering of the U.S. tolerance for citrus fruit.

22 (continued)

Table D. (continued)

Commodity	Codex MRL (ppm)	U.S Tolerance (ppm) <sup>a</sup>	Compatibility/Comments
Sheep fat	0.02	None	The current U.S. tolerance of 0.05 ppm will be revoked.
Sorghum	0.1	0.2 (grain) 2 (forage, fodder)	The current use pattern for methidathion on sorghum does not permit a lowering of the U.S. Tolerances.
Tea, green, black	0.1	None	
Tomato	0.1	None	

<sup>&</sup>lt;sup>a</sup> Reassessed U.S. tolerance levels are given.

## AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No: 13714

DP Barcode: D203435

Subject: Response to the Methidathion Reregistration Standard: Livestock Metabolism

Upgrade.

From: R. Perfetti, PhD., CBRS To: L. Schnaubelt, SRRD

Dated: July 6, 1995

MRID(s): 43170001 and 43170005

CBTS No: 14096

DP Barcode: D205743

Subject: ID# 000100-00754. Label Amendment for Methidathion (Supracide 25WP®

Insecticide-Miticide).

From: G. Kramer, Ph.D., CBTS

To: D. Edwards, Jr./P. Jenkins & J. Smith, IRB & HED

Dated: April 27, 1995

MRID(s): 43308801, 43308802, 43308803 and 43308804

CBRS No: None

DP Barcode: D210041

Subject: The HED Metabolism Committee Meeting held on April 4, 1995: Methidathion.

From: R. Perfetti, Ph.D., CBRS
To: Metabolism Committee, HED

Dated: April 6, 1995

MRID(s): 43399701 and 43399702

CBRS No: 14000

DP Barcode: D205407

Subject: Response to the Methidathion Reregistration Standard: Independent Lab Validation.

From: R. Perfetti, Ph.D., CBRS

To: E. Saito, SRRD Dated: January 6, 1995

MRID(s): 43296401 and 43296402

CBTS No: 13982 and 13983

DP Barcode: D204948 and D204952

Subject: WA940019 and WA940020. Special Local Need [24(c)] Registration for Application

of Supracide 2E® and Supracide 25W® (Methidathion, EPA Reg.#100-501 and 100-

754, respectively) to Timothy or Timothy-Alfalfa Stands.

From: G. Herndon, CBTS

To: D. Edwards, Jr./P. Jenkins, IRB

Dated: July 28, 1994

MRID(s): None

CBTS No: 13529 and 13530

DP Barcode: D216609 and D216616

Subject: WA940019 and WA940020. Special Local Need [24(c)] Registration for Application

of Supracide 2E® and Supracide 25W® (Methidathion, EPA Reg.#100-501 and 100-

754, respectively) to Timothy or Timothy-Alfalfa Stands.

From: J. Garbus, CBTS

To: D. Edwards, Jr./P. Jenkins, IRB

Dated: May 9, 1994

MRID(s): None

CBRS No: 12331

DP Barcode: D193876

Subject: Response to the Methidathion Reregistration Standard: Confined Rotational Crops.

From: R. Perfetti, Ph.D., CBRS

To: L. Rossi, SRRD Dated: December 20, 1993 MRID(s): 40094101, 41902201

CBRS No: None

DP Barcode: None

Subject: Methidathion and its Metabolites.

From: L. Edwards, CBRS
To: H. Hundley, BEAD
Dated: September 17, 1993

MRID(s): 42537106

CBRS No: 11683

DP Barcode: D189970

Subject: Response to the Methidathion Reregistration Standard

From: R. Perfetti, PhD., CBRS

To: L. Rossi, SRRD Dated: July 28, 1993

MRID(s): 42708901, 42708902, 42708903

CBRS Nos: 10870 and 11158

DP Barcodes: D184576 and D186643

Subject: Response to the Methidathion Reregistration Standard

From: R. Perfetti, PhD., CBRS

To: Lois Rossi, SRRD and E. Saito, HED

Dated: March 2, 1993

MRID(s): 42537101, 42537102, 42537103, 42537104, 42537107, 42537108, 42537109,

42537110, 42537111

CBRS No: 8422

DP Barcode: D167356

Subject: Response to the Methidathion Reregistration Standard

From: R. Perfetti, PhD., CBRS

To: L. Rossi, SRRD Dated: April 1, 1992 MRID(s): 41902201

**CBTS No: 7298** 

DP Barcode: D158422

Subject: Methidathion in/on Sugar Apple

From: W. Wassell

To: H. Jamerson, RD Dated: April 22, 1991

MRID(s): 41686301, 41686302

**CBTS No: 5538** 

DP Barcode: None

Subject: PP#9E3769. Methidathion (Supracide® 2E Insecticide-Miticide) in or on Longan

and Carambola.

From: F. Toghrol, Ph.D., DEB
To: H. Jamerson, HED
Dated: October 24, 1989

MRID(s): 41151801

**CBRS No: 5140** 

DP Barcode: None

Subject: Ciba-Geigy's Response to the Methidathion Registration Standard

From: R. Schmitt, DEB

To: R. Engler, SACB and L. Rossi, SRRD

Dated: January 4, 1989

MRID(s): 41021401 and 41151802

**CBTS No: 4769** 

DP Barcode: None

Subject: Methidathion in/on Kiwifruit

From: M. Nelson
To: H. Jamerson
Dated: March 16, 1989

MRID(s): 40931301

## MASTER RECORD IDENTIFICATION NUMBERS

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